CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE

MEMORANDUM

TO: Members of the ICOC

FROM: C. Scott Tocher, Counsel to the Chair

RE: **Item 17:** Intellectual Property Regulations Consolidation Project

DATE: September 15, 2008

Executive Summary

At the ICOC's September 25, 2008 meeting, staff will seek Board approval for a project that (a) consolidates the intellectual property regulations for Non-Profit Grantees and the intellectual property regulations for For-Profit Grantees into a single set of regulations, and (b) clarifies the scope of certain regulations. This memorandum sets forth the justification for the proposed project.

As you know, Proposition 71 required the ICOC to adopt policies that balance competing benefits to California from patents, royalties and licenses, while assuring that essential research is not unreasonably hindered by intellectual property agreements. To that end, the ICOC adopted regulations implementing two intellectual property policies, one set for non-profit grantees and one for for-profit grantees. These regulations were carefully crafted after dozens of interviews, public meetings of the Intellectual Property Task Force, hundreds of public comments and presentations by experts and stakeholders. The regulations strike the appropriate balance in the areas of revenue sharing, biomedical materials sharing and access provisions, to name a few. As CIRM matures and the structures for research proposed by grantees become more complicated, the need to clarify existing regulations has become apparent. For instance, collaborations between and among both non- and for-profit sectors suggest that a single uniform policy (and set of regulations) will be easier for our grantees to understand and for CIRM to administer. The goal of the consolidation project is not to reopen the issues settled in the policies or to materially reset the balance made therein – rather, the project will harmonize the two into a single set of regulations better provide greater definition to the scope and application of the policies themselves.

I. Authority

Proposition 71 empowers the ICOC to adopt rules and regulations to carry out the purposes of the Proposition. (Health & Safety Code § 125290.40, subd. (j).)

II. Background

The adoption of policies and their transformation into formal regulations is a complicated process governed by the Administrative Procedures Act ("APA"), which is administered by the Office of Administrative Law ("OAL"). Generally speaking, this multi-step process begins with the preparation by the task force of a draft policy, which in turn is approved by the ICOC as an interim policy. From that document, staff translates the elements of the policy into formal regulatory language and submits the regulations ("notices") to the OAL. This commences the one-year period for the agency to fine-tune the regulations through a series of drafts and changes derived from public input. When all the comments have been received and there are no further changes to the draft regulations, they are brought before the ICOC for final adoption and then sent to the OAL, which conducts an exhaustive review of the regulations. If approved by the OAL, the regulations are published by the Secretary of State and have the force and effect of law.

In this process, the IP Task Force and ICOC held at least 15 public meetings devoted to the IP policy development, observed 18 public presentations by experts and stakeholders, surveyed the best practices of more than 20 funding entities, conducted over 100 interviews, refined the regulations over 12 public comment rounds and responded in detail to more than 100 comment letters according the APA.

Pursuant to Proposition 71's mandate to provide for a return to the State of California on its investment of state resources in stem cell research, CIRM propounded policies and regulations through the ICOC and the Intellectual Property Task Force that will ensure a fair return on investment while assuring that research is not unduly hindered.

The application of the existing regulations turns on the type of grant recipient – commercial versus noncommercial. The ICOC first approved an intellectual property policy for non-profit and academic research institutions, as those institutions were the first recipients of CIRM grants. That policy, initially adopted in February of 2006, completed the formal regulatory adoption process and went into effect in 2007. The formal adoption of regulations governing for-profit institutions began during the development of the non-profit policy and concluded earlier this year.

Staff has received many questions about the scope and application of both sets of regulations since adoption. Many of these questions came from potential commercial sector participants and from academic institutions planning to collaborate with commercial entities on grant applications. In response to these inquiries, and in an effort to encourage vital commercial sector participation in CIRM programs, on September 11 and 12, 2008, Nancy Koch, Scott Tocher and Ed Penhoet, Chair of the ICOC's IP Task Force, conducted IP educational workshops in San Francisco and San Diego. The afternoon sessions provided an opportunity to answer questions about specific

requirements and provisions of CIRM's IP regulations for attorneys, executives and scientists from for-profit companies and academic scientists and administrators who will be working in collaboration with for-profit companies. The sessions were well-attended – approximately 100 people participated. The feedback from participants suggests that a consolidation and clarification effort would be well received by CIRM's grantees.

III. Scope

To reiterate, the purpose of the consolidation project is not to reexamine the issues already decided by the ICOC in the promulgation of the existing IP regulations. In other words, the intent of the project is not to reconsider requirements relating to access plans and pricing provisions for uninsured and underinsured Californians. Nor is the project intended to revisit the threshold requirement that grantees are bound by the regulations with receipt of the first CIRM dollar or whether CIRM should require its grantees to share publication-related biomedical materials. Rather, the focus of the project will be to identify those regulations that might benefit from further clarification as to their scope and give further meaning to the ICOC's intent in circumstances not explicitly addressed in the regulations.

CIRM and ICOC counsel, assisted by outside counsel and the feedback provided during the IP workshops, have identified certain areas for clarification, some examples of which are discussed below. The types of clarifications may be categorized two ways: 1) harmonizing changes; and 2) scope clarifications.

A. Harmonizing Changes:

As discussed above, the non-profit and for-profit policies were developed at different times (the for-profit policy was finalized a year after the non-profit policy). As a consequence, certain policy components in the for-profit context benefitted from the additional time that elapsed in the development of that policy. For instance, the definitions of "exclusive license" and "grantee" are similar but different in subtle but potentially material ways. The project will examine the respective definitions and recommend a uniform set of definitions that will apply in all contexts.

B. Scope Clarifications:

The contemplation of various forms of collaboration among for- and non-profit organizations reveals areas of the regulations that might profit from further explication. For instance, the regulations are premised on the relationship of grantees and their exclusive licensees (the obligations of the grantee flow to an exclusive licensee). One might imagine, however, structures of transferring IP rights other than by license – such as selling the IP to a new owner. Also, the regulations presently refer to U.S. patents, though foreign IP and related revenues were intended to fall within the scope of the regulations. And in the context of collaborative efforts, defining which entity is the grantee and describing how the regulations will apply to the collaborators will clarify the rights and responsibilities of the parties to those grants. Finally, clarifying the term "in

whole or in part" and how the ICOC intends its regulations to reach drugs or therapies that might use knowledge or data created with CIRM funding but that were not be directly funded by CIRM, or other more remote scenarios, will go a long way to establish the outer parameters of the regulations' reach.

IV. Process

With approval at this meeting by the ICOC, staff will take the issues identified above, identify others and draft language to clarify how the regulations apply in the given circumstances. The language will be reviewed at a meeting of the IP Task Force in October before being noticed with the OAL to begin the process of obtaining formal public comment. The process will mirror that which the IP Task Force conducted in formulating the initial policies and regulations and for which the task force received wide praise. The ICOC will be updated at subsequent board meetings prior to the ICOC's final consideration of adoption of the revised regulations. This timeline will ensure that the final revisions are in place before the Notices of Grant Award for Translational and Disease Team grants are executed in 2009.

Recommendation: Staff recommends the ICOC direct staff to conduct the consolidation project for IP regulations described above and initiate the processes to do so as described in Section IV of this memorandum.